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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,607	12/08/2000	Giulio Tononi	P-N1 4447	4199

23601 7590 08/18/2004  
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EXAMINER
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WEGERT, SANDRA L.

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

319

**Advisory Action**

Application No.

09/733,607

Applicant(s)

TONONI ET AL.

Examiner

Sandra Wegert

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 12 and 13.

Claim(s) withdrawn from consideration: 1-11, 14 and 15.

*Elizabeth C. Hammer*

ELIZABETH C. HAMMER  
PRIMARY EXAMINER

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of Claims 12 and 13 under 35 USC 112, Scope of Enablement, is maintained for the reasons of record in the previous Office Action. Briefly, the Specification enables a method of studying a vigilance disorder in DAT(lo) flies, but does not enable a method of finding a compound that modulates a vigilance disorder in mammals that may include humans. No nexus has been established between flies lacking dopamine acetyltransferase and a comparable disorder in humans. Additionally, there is a lack of detail and specificity concerning the correlation of specific diseases with the claimed genes. Allowable claims might list each disorder that can be diagnosed in animals and humans (since the claims encompass "individuals") as well as that disorder's corresponding gene profile. The contention that one could select a vigilance disorder and find the corresponding gene profile (17 March 2004, page 7) is unacceptable since a patent application must be complete at filing (Brenner v. Manson, 1966, 148 U.S.P.Q. 689- "a patent is not a hunting license"). The Specification, besides not enabling one to correlate a gene profile with a disorder in humans, has not demonstrated a correlation between the claimed genes in humans and those in other species, or has not demonstrated the criteria for establishing why the genes are considered homologous. Several examples that establish such a nexus between human genes and non-human genes as well as between human diseases and conditions in animals would go a long way toward enabling the instant invention. p450 enzymes, for example, do not correlate well between and among species either in terms of name or function.

The rejection of Claims 12 and 13 under 35 USC 112, Indefiniteness, is maintained for the reasons of record in the previous Office Action. Applicants have not defined a "vigilance" disorder or "vigilance" genes beyond a recitation of many unrelated disorders that only resemble each other inasmuch as they appear to be related to sleep cycles or diurnal activity levels.